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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,720	04/01/2004	Roeland Nusse	STAN-299	1120

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EXAMINER	
CHISM, BILLY D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/816,720	NUSSE ET AL.	
	Examiner	Art Unit	
	B. Dell Chism	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) 1-6 and 12 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 7-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11-18-04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. During a telephone conversation with Pam Sherwood on 24 March 2005 a provisional election was made with traverse to prosecute the invention of Group III, claims 7-11. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-12 are pending and Claims 1-6 and 12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to compositions comprising Wnt protein, classified in class 514, subclass 13.

II. Claim 6, drawn to methods of enhancing stem cell proliferation using a Wnt protein, classified in class 514, subclass 13.

III. Claims 7-11, drawn to methods of isolating Wnt proteins, classified in class 530, subclass 344.

IV. Claim 12, drawn to method of inhibiting mediated signaling, classified in class 514, subclass 13.

3. The inventions are distinct, each from the other because:

Groups II-IV are independent inventions wherein the three groups of methods are independent, using separate method steps, active agents, and having different effects. Groups II and IV are methods treating and Group III is a method of isolating the Wnt protein.

The product of Group I is related to the methods of Group III as a product and process of making the product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed may be made by chemical peptide synthesis. Group III is to methods of making a substantially homogenous composition that is the product of Group I, which can be made by chemical peptide synthesis.

Groups I is distinct from Groups II and IV as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be use in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein composition of Group I can be used for molecular weight markers or to make antibodies.

4. Because these inventions are distinct for the reasons given above and the search required for one group is not required or necessarily inclusive of searches for other groups, restriction for examination purposes as indicated is proper.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Specification

6. The disclosure is objected to because of the following informalities: page 25 of the specification refers to an amino acid sequence, however, the sequence has no sequence identifier. Consequently, 37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 7 is indefinite wherein it is unclear as to whether the claim is drawn to "isolating a Wnt protein" to have a "substantially homogenous" Wnt protein or if the claim is drawn to making a composition comprising Wnt protein that was isolated and purified to put into a composition. Additionally, there are missing method steps in the claim. There appears to be both an isolation phase and a purification phase. There is no identification as to from what the

Wnt is being isolated and/or purified. Thus, the claim is incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

10. Claims 8-11 are rejected for depending from rejected claims.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claim 7 is rejected under 35 U.S.C. 102(e) as being anticipated by Rodan et al. (US 5,780,291). Rodan et al. teaches the purification of an Wnt protein by affinity chromatography in the presence of detergents (column 15, lines 1-24) as claimed in the instant claim 7. Claim 7 claims purification of Wnt by affinity chromatography in the presence of detergents, and this taught, as cited above, by Rodan et al.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 7-11 rejected under 35 U.S.C. 103(a) as being unpatentable over Rodan et al. (US 5,780,291) in further view of Lambeth et al. (US 6,620,603 B1), Vernet et al. (US 6,653,448 B1), and Matthews et al. (US 6,159,462).

The instant claims are drawn to purification/isolation methods for Wnt proteins by affinity chromatography (e.g., dye-ligand) in the presence of detergents, followed by gel-exclusion chromatography and cation exchange chromatography. Rodan et al. teaches the use of affinity chromatography for purification of Wnt proteins in the presence of detergents (column 15, lines 1-24). Rodan et al. also teaches the relevance of purifying Wnt proteins for production of therapeutic agents (Column 7, lines 44-51). Rodan et al. also teaches purification of Wnt through the use of size exclusion chromatography, which would include gel exclusion, and ion exchange chromatography, which would include cation exchange. These types of purification techniques are well known in the protein arts as demonstrated by Lambeth et al. Lambeth et al. does not teach Wnt peptides, but does teach the techniques as are currently claimed for the purification of naturally occurring or expressed proteins (Column 17, lines 62-67). Lambeth et al. teaches protein purification by cation exchange chromatography, dye binding chromatography and gel exclusion chromatography (Column 17, lines 62-67). As in the both Rodan et al. and Lambeth et al. it would be obvious to one of ordinary skill in the art to utilize the purification steps especially where there is a desire to use the purified product in a pharmaceutical composition as discussed in Rodan et al. Furthermore, these references do not teach a sequence of purifications by one chromatography followed by another type of chromatography as in the instant claims; however, it would be obvious to one of ordinary skill in the art to use the multiple

purification steps wherein the purification steps of affinity chromatography (dye) along with size exclusion chromatography (gel) and ionic exchange chromatography (cation) would only further purify the Wnt based on different aspects of the compounds, i.e., size, charge, etc..., and to use the Wnt product of the further purifications for pharmaceutical purposes as stated in Rodan et al.

Rodan et al. teaches purifying Wnt protein from cell lysates and extracts or from continued culture medium (Column 5, lines 12-25). Matthews et al. (US 6,159,462) teaches substantially homogenous Wnt proteins purified via affinity chromatography and cation-exchange resins along with the need to utilize detergents (column 23, lines 49-65).

Therefore, it would be obvious to one of ordinary skill in the art at the time of filing, to purify a Wnt peptide via affinity (dye) chromatography in the presence of detergents for solubility. And to further purify based on other structural characteristics such as size and charge by the use of gel exclusion chromatography and cation exchange chromatography, for the purpose of making pharmaceutical compositions comprising the Wnt proteins. Finally, a purified product of Wnt proteins would be expected since the methods are well known in the art and would be obvious to use by one of ordinary skill in the art.

Conclusion

15. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism, whose telephone number is (571) 272-0962. The examiner can normally be reached on M-F 08:30 AM - 5:00 PM. If attempts to reach the

examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, PhD can be reached on (571) 272-0974.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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B. Dell Chism 

PATENT EXAMINER